



#18

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Attorney Docket No. 046601-15001

Group Art Unit: 3736)
Examiner: Robert L. Nasser)
Inventors: Torok *et al.*)
Serial No.: 09/758,978)
Filed: January 12, 2001)
For: SYSTEM FOR IDENTIFYING)
PREMATURE RUPTURE OF)
MEMBRANE DURING)
PREGNANCY)

**APPEAL
BRIEF**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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DEC 19 2003
TECHNOLOGY CENTER R3700

This is an appeal to the Board of Patent Appeals and Interferences from a final decision of Examiner Robert L. Nasser mailed January 10, 2003. Claims 1 and 13 through 16 are finally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 through 20 of U.S. Patent No. 6,126,597. Claims 2 through 5, 7 through 11, 13 through 16 and 31 through 34 are finally rejected under 35 U.S.C. Section 102(e). A Notice of Appeal was timely filed in the U.S. Patent and Trademark Office under the certificate of mailing procedure on June 10, 2003.

12/17/2003 MDAMTE1 00000117 041061 09758978

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I. Real Party In Interest

The real party in interest is Horizons Health Products for Women, LLC, 960 West 11 Mile Road, Berkley, Michigan 48072. This application is a continuation-in-part of United States patent application No. 09/595,594, filed June 15, 2000, which is a continuation-in-part of 09/351,875, issued on July 13, 1999, as U.S. Patent No. 6,149,590, which is a continuation-in-part of 09/120,829, issued on July 22, 1998, as U.S. Patent No. 6,126,597. These applications are assigned to Horizons Health Products for Women, LLC, by way of an assignments recorded at Reel 011789, Frame 0014, on May 8, 2001, and Reel 012330, Frame 0795, on November 30, 2001. The present application is assigned to Horizons Health Products for Women, LLC, by way of an assignment recorded in connection with this application at Reel 011735, Frame 0428, on April 27, 2001.

II. Related Appeals and Interferences

There are no related appeals or interferences known to Appellants, Appellants' legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 2 through 5, 7 through 11, 13 through 16, and 31 through 34 are pending and finally rejected. Appellants appeal with respect to all of these

claims.

IV. Status of Amendments

Appellants filed their Responsive Paper-B on June 10, 2003, which was filed after final rejection. The amendments set forth in this paper were not entered.

V. Summary of the Invention

The present application discloses and claims an article for the identification of the premature rupture of a membrane during pregnancy. The invention is portrayed in several embodiments. The embodiment of the claims being appealed is directed to the use of a non-irritating, pH-sensitive material that is applied to an indicating article in the form of a pad that is fitted to the undergarment of a wearer. The pH-sensitive material applied to the pad responds by way of a visualizable color change to the presence of amniotic fluid as a discharge.

VI. Issues

A. Whether the double patenting rejection has been overcome.

B. Whether the appealed claims are novel and unanticipated by Japanese reference JP 5-123324 to Yazaki under 35 U.S.C. Section 102(e).

VII. Grouping of Claims

Claims 2 through 5, 7 through 11, 13 through 16, and 31 through 34 stand or fall together as a single group.

VIII. Arguments

The rejection of the claims under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 through 26 of co-pending Application No. 09/793,722 is overcome and should be reversed. The rejection of the claims under 35 U.S.C. Section 102(e) is improper and should be reversed as it is not supportable.

A. Double Patenting

The double patenting rejection should be reversed.

In the Office Action mailed April 25, 2002, the Examiner rejected Claims 1 and 13 through 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 through 20 of U.S. Patent No. 6,126,597. Appellants filed a response to this Office Action on October 25, 2002, by way of an Amendment and Request for Reconsideration Under 37 C.F.R. Section 1.111 as well as a Terminal Disclaimer. While no fee was included, authorization was given to charge a Deposit Account in both in the response transmittal as well as in the last page of the Terminal Disclaimer.

In the Office Action mailed January 10, 2003, the Examiner stated that

because the fee was omitted, the double-patenting rejection still remained.

Appellants state that the double-patenting rejection was overcome in their response of October 25, 2002, because authorization to charge the deposit account was given. The undersigned attorney for Appellants left his prior law firm in May 2003 but hereby authorizes the fee for the Terminal Disclaimer to be charged to his current firm's Deposit Account of 04-1061 if this will help to remedy the issue of non-payment of the Terminal Disclaimer fee.

B. Rejection Under 35 U.S.C. Section 102(e)

The rejection under 35 U.S.C. Section 102(e) is improper and should be reversed.

The first substantive response received from the U.S. Patent & Trademark Office on the present application was mailed March 12, 2002, and was a restriction requirement.

Appellants made a timely election in response to this paper.

The second substantive response received from the U.S. Patent & Trademark Office on the present application was mailed April 25, 2002, and (1) confirmed Appellants' election, (2) rejected Claims 1 and 13 through 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 through 20 of U.S. Patent No. 6,126,597, and rejected Claims 1 through 17 and 31 through 34 under 35 U.S.C. Section 102(e) as being anticipated by Yazaki JP 5-123324 (hereinafter referred to as "Yazaki").

Appellants responded by (1) filing a terminal disclaimer with respect to

U.S. Patent No. 6,126,597 and (2) arguing against the Section 102(e) rejection. With respect to the latter response, Appellants stated that Yazaki failed to teach every element of the claim as required to qualify as an anticipating reference. Specifically, Appellants pointed out that Yazaki did not teach or suggest the claimed system and method which did "not have a sheet that is impregnated with a pH indicating material and [was] covered with extra layer of cloth. For the present invention, a pH-sensitive material is applied to the surface of an article, which is for wearing substantially adjacent the crotch of a pregnant woman. Thus, according to the invention, the pH-sensitive material will be in direct contact with the skin of the woman or is applied to the skin of the woman, which renders a more precise and accurate determination of the amenorrhexis." (Appellants' response of October 25, 2002, page 4, lines 23-29.) Appellants argued that Yazaki thus failed to teach or suggest every element of the claims.

The third substantive response received from the U.S. Patent & Trademark Office on the present application was a *final* response mailed January 10, 2003, and (1) stated that the fee for the terminal disclaimer was omitted and (2) rejected Claims 2 through 5, 7 through 11, 13 through 16, and 31 through 34 under 35 U.S.C. Section 102(e) as being anticipated by Yazaki.

The Examiner stated "*Applicant has argued that the color indicator of Yazaki is not substantial (sic) adjacent the crotch because it is below the cloth layer. The examiner notes that applicant has not defined the term substantially adjacent. In addition, applicant's layer is between sheets 26 and 28. Accordingly, the examiner disagrees with applicant.*"

Appellants responded by (1) canceling Claims 1 and 13 through 16 and

(2) amending Claims 2 and 7 to delete the language "substantially adjacent" and to define the article as including an upper layer that is in contact with the crotch of the pregnant woman. In addition, Appellants argued that "Yazaki teaches nothing about the application of a pH-sensitive material to the upper surface of an article for wearing by a pregnant woman. In addition, Yazaki teaches nothing about a pH-sensitive material that is non-irritating to the wearer." (Appellants' Amendment-B mailed June 20, 2003, page 5, lines 10-13.)

The fourth substantive response received from the U.S. Patent & Trademark Office on the present application was an Advisory Action mailed June 25, 2003, which stated that the Appellants reply filed June 10, 2003, failed to place the application in condition for allowance.

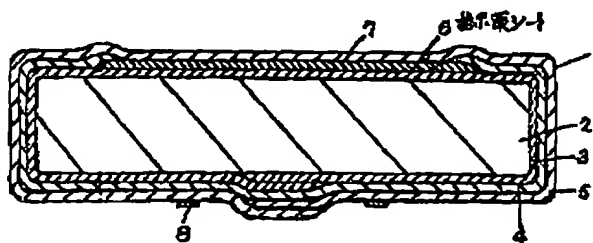
"[A]nticipation requires that all elements and limitations of the claim are found within a single prior art reference." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 U.S.P.Q.2d 1001, 1010, 927 F.2d 1565, 1576 (Fed. Cir. 1991). It is well settled that anticipation can only be established by a single prior art reference which identically discloses each and every element of the claimed invention. Anticipation is not established even if the differences between the claims and the prior art reference are insubstantial. To the contrary, the cited reference must show exactly what is claimed. *In re Bond*, 15 U.S.P.Q.2d 1566, 910 F.2d 831 (Fed. Cir. 1990) (For a prior art reference to anticipate, every element of the claimed invention must be identically shown and arranged as in the claimed invention); *Structural Rubber Prod. Co. v. Park Rubber Co.*, 223 U.S.P.Q.2d 1264, 749 F.2d 707 (Fed. Cir. 1984). In *Scripps Clinic*, *supra* at 1010, the Federal Circuit held that for anticipation there "must be no difference

between the claimed invention and the reference disclosure, as viewed by one of ordinary skill in the field of the invention."

Appellants respectfully submit that Yazaki does not show that which is claimed. First, with respect to the construction of the Yazaki pad, the general pad structure is as follows:

"In the figures, 1 is an absorbing pad, which comprises of an (sic) absorbing body 2 made by stacking cotton pulps, an unwoven cloth 3 which wraps absorbing body 2 and are stacked on top of each other on the bottom surface thereof, watertight laminate paper which wraps around the bottom surface, both side surfaces and parts of the top surface of unwoven cloth 3 excepts its middle of the top surface, and an unwoven cloth 5 which wraps the outer surface of laminate paper 4 and are stacked on top of each other on the bottom surface thereof." (Yazaki, paragraph [0008], page 5)

The Yazaki figure appears below:



The pH indication agent sheet is disposed *within* the pad 1:

"In the figure, 6 is a pH indication agent sheet, in which a sheet 7 made of paper cotton or cloth is wet with a pH indication agent, bromthymol blue (hereafter, BTB). A piece of sheet 7 with a width of 50mm, or 2 ~ 4 pieces of

narrower sheet 7 with a width of 0.5cm ~ 1.5cm are inserted along the longitudinal direction of pad 1 between the middle section of the top surface of unwoven cloth 3 and unwoven cloth 5." (Yazaki, paragraph [0009], page 5)

Accordingly, the watertight laminate paper 4 wraps around the unwoven cloth 3 with the exception of the middle part of the top surface of the cloth 3, thereby exposing the cloth 3 at its top surface portion. The pH indication agent sheet 6 is wet with BTB and is placed on the exposed surface of the cloth 3 and between the unwoven cloth 3 and the woven cloth 5. In this manner *the sheet 6 is placed underneath the unwoven cloth 5 and will not and cannot be brought into contact with the skin of the wearer.*

In his Office Action mailed June 10, 2003, the Examiner stated that *"applicant's layer is between sheets 26 and 28."* This is true with respect to the embodiment shown in Figures 1 through 5 and discussed in relation to these figures. However, this is *not* true with respect to the embodiment claimed and shown in Figure 6. This figure "is a perspective view of an alternate embodiment of the present invention in the form of a pH-indicating fluid being distributed on a feminine hygiene pad." (Application as filed, page 5, lines 31 – 33.) According to this embodiment, "[t]he wearer (not shown) would apply a series of drops of the liquid material along the approximate mid-point of the *upper, body-facing* side of a pad or napkin 40." (Application as filed, page 10, lines 14 – 16; emphasis added.) And, more broadly, "such [pH-sensitive] material may be applied to the pad or other article intended for this purpose in the form of liquid drops, an atomized spray (which may be from a pressurized aerosol container), a sprayed liquid (which may be from an aerosol or pump spray container), a

powder, a sheet or solid pH-sensitive material (in the form of a strip), or a gel material." (Application as filed, page 11, lines 38 – 39, and page 12, lines 1 – 4.)

Applying these facts to the legal principles set forth above establishes that the subject matter of the appealed claims is not anticipated by Yazaki. First, each and every element of the claimed invention is not disclosed in Yazaki. Second, one of ordinary skill in the art would not conclude that there is no difference between the pad of Yazaki and the invention of the present claims.

Accordingly, Appellants respectfully submit that the Examiner's rejection under 35 U.S.C. Section 102(e) is improper and should be overturned.

Although the claims are not rejected under 35 U.S.C. Section 103, Appellants further submit that the subject matter of the claims is not obvious in view of Yazaki. The Yazaki pad would have to be extensively modified to render the present invention obvious in its light. As mentioned above, Yazaki fails to show a pad on which a *non-irritating* pH-sensitive material is *externally applied*. It is well settled that the fact that a prior art apparatus can be modified so as to produce the claimed invention is not a basis for an obviousness rejection unless the prior art suggested the desirability of such a modification. *In re Laskowski*, 10 U.S.P.Q.2d 1397, 871 F.2d 115 (Fed. Cir. 1989); *In re Gordon*, 221 U.S.P.Q. 1125, 733 F.2d 900 (Fed. Cir. 1984) Appellants respectfully submit that it would be improper to reject the pending claims as being obvious in view of Yazaki because the prior art fails to provide a motivation for making the suggested modification.

Clearly Yazaki fails to teach, suggest, disclose, or otherwise render obvious the present invention. In fact, Yazaki clearly teaches away from such

an arrangement on at least two grounds. First, the pH-sensitive material is disposed *within* the Yazaki pad, and is thus removed from direct contact with the skin. Second, the pH-sensitive material of Yazaki – bromthymol blue - is a known skin irritant, as set forth in the attached Exhibits A and B. It is clear that Yazaki would *not* want to place this material in contact with the wearer's skin. Negative teachings in the prior art are regarded as evidence of non-obviousness. *Mobil Oil Corp. v. W.R. Grace & Co.*, 180 U.S.P.Q. 418, 367 F. Supp. 207 (Conn. 1973).

In addition, even if Appellants were claiming a pH-sensitive element provided *within* their pad as is the case in Yazaki, this reference would still would not render the present invention obvious. Yazaki's placement of a "sheet 7 made of paper cotton or cloth [that] is wet with a pH indication agent, bromthymol blue" does not necessarily avoid the skin-irritating nature of the chemical composition. This arrangement of a sheet containing a known skin-irritant *within* the pad still teaches away from the embodiment of the present invention in which the pH-sensitive material is disposed within the pad (the embodiment of Figures 1 through 5). In Yazaki, only a layer of unwoven cloth separates the bromthymol blue-wetted sheet from the wearer's body. By definition, the unwoven cloth allows fluids to pass from the outside of the pad to the inside. This unwoven cloth barrier is not a one-way barrier, so by definition fluids – including leached bromthymol blue - can pass in the reverse direction, that is, from the bromthymol blue-saturated sheet to the skin of the wearer. By using a non-irritating pH indicator, the present invention is patentably different from Yazaki in all of its embodiments.

Because Yazaki does not disclose what is claimed and because Yazaki would not otherwise render the present invention obvious, Appellants respectfully submit that the Examiner's rejection on the basis of prior art is in error and should be reversed.

CONCLUSION

Appellants respectfully submit that the Examiner's double patenting rejection and the rejection under 35 U.S.C. Section 102(e) are in error and should be reversed.

An oral hearing is respectfully requested.

The required Appeal Fee is submitted herewith, together with a fee for the requisite extensions of time.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'T. Moga', with a long horizontal flourish extending to the right.

Thomas T. Moga
Registration No. 34,881
Attorney for Appellants

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1901 L Street, N.W., Suite 800
Washington, D.C. 20036
202-457-0160

Dated: **December 10, 2003**

IX. Appendix

-2-

A method for use by a pregnant woman for identifying the premature rupture of a membrane during pregnancy, the method comprising the sequential steps of:

forming an article for wearing substantially adjacent the crotch of the pregnant woman;

applying to said article a pH-sensitive material capable of responding by way of a visible change to the presence of a fluid with a pH in the range of amniotic fluid, said pH-sensitive material being non-irritating to the woman and having a readily applicable form, said form being selected from the group consisting of liquid drops, atomized spray, aerosol liquid, powder, gel, and a solid;

wearing said article for a period of time; and

visualizing said pH-sensitive material for a visible change

-3-

The method of Claim 2, wherein said article for wearing is an undergarment.

-4-

The method of Claim 2, wherein said article for wearing is a pad.

-5-

The method of Claim 2, wherein said article for wearing is a fluid collecting device.

-7-

A method for use by a pregnant woman for identifying the premature rupture of a membrane during pregnancy, the method comprising the sequential steps of:

forming an article for wearing substantially adjacent the crotch of the pregnant woman;

wearing said article for a period of time;

applying to said article a pH-sensitive material capable of responding by way of a visible change to the presence of a fluid with a pH in the range of amniotic fluid, said pH-sensitive material being non-irritating to the woman; and visualizing said pH-sensitive material for a visible change.

-8-

The method of Claim 7, wherein said pH-sensitive material is provided

in a readily applicable form, said form being selected from the group consisting of liquid drops, atomized spray, aerosol liquid, powder, gel, and a solid.

-9-

The method of Claim 7, wherein said article for wearing is an undergarment.

-10-

The method of Claim 7, wherein said article for wearing is a pad.

-11-

The method of Claim 7, wherein said article for wearing is a fluid collecting device.

-13-

A system for use by a pregnant woman for identifying the premature rupture of a membrane during pregnancy by detecting the presence of amniotic fluid outside the amnion, the system comprising:

an article for wearing substantially adjacent the crotch of a pregnant woman; and

a pH-sensitive material capable of responding by way of a visible

change to the presence of fluid with a pH in the range of amniotic fluid, said material being applicable by the woman to said article prior to said article being worn, the pH-sensitive material being non-irritating to the woman and having a form selected from the group consisting of liquid drops, an atomized spray, an aerosol liquid, a powder, a gel, and a solid;

whereby the woman visualizes said article after wearing said article to observe a visual change.

-14-

The system of Claim 13, wherein said article for wearing is an undergarment.

-15-

The system of Claim 13, wherein said article for wearing is a pad.

-16-

The system of Claim 13, wherein said article for wearing is a fluid collecting device.

-31-

A method for use by a pregnant woman for identifying the premature

rupture of a membrane during pregnancy by detecting the presence of amniotic fluid outside the amnion, the method comprising:

applying to a surface which is suspected to have amniotic fluid a pH-sensitive material capable of responding by way of a visible change to the presence of a fluid having a pH in the range of amniotic fluid, said pH-sensitive material being selected from the group consisting of a solid, a liquid, and a gel, and said pH-sensitive material being non-irritating to the woman.

-32-

The method of Claim 31, wherein said surface is skin.

-33-

The method of Claim 31, wherein said solid is in a form taken from the group consisting of a powder and a solid in the form of a sheet or a strip.

34. The method of Claim 31, wherein said liquid is in a form taken from the group consisting of drops, atomized spray, and aerosol.

ORBECO ANAYLTICAL SYSTEMS INC -- BROMTHYMOL BLUE INDICATOR SOLN, 170-S -- 6505-00N03

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MSDS Safety Information

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FSC: 6505
MSDS Date: 06/19/1992
MSDS Num: BQMQL
LIIN: 00N036198
Tech Review: 11/10/1992
Product ID: BROMTHYMOL BLUE INDICATOR SOLN, 170-S
Responsible Party
Cage: IO419
Name: ORBECO ANAYLTICAL SYSTEMS INC
Address: 185 MARINE ST
City: FARMINGDALE NY 11735 US
Info Phone Number: 516-293-4110
Emergency Phone Number: 516-293-4110
Review Ind: N

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Contractor Summary

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Cage: 90767
Name: ORBECO ANALYTICAL SYSTEMS INC
Address: 185 MARINE ST
City: FARMINGDALE NY 11735 US
Phone: 516-293-4110
Cage: IO419
Name: ORBECO ANAYLTICAL SYSTEMS INC
Address: 185 MARINE ST
City: FARMINGDALE NY 11735 US
Phone: 516-293-4110

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Ingredients

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Cas: 76-59-5
RTECS #: SJ7450000
Name: 4,4'-(3H-2,1-BENZOXATHIOL-3-YLIDENE)
BIS(2-BROMO-3-METHYL-6-(1-METHYLETHYL)-, S,S-DIOXIDE; (BROMTHYMOL BLUE)
% by Wt: 0.1
Ozone Depleting Chemical: N

Cas: 67-56-1
RTECS #: PC1400000
Name: METHANOL
% by Wt: 20
OSHA PEL: S,200PPM/250STEL
ACGIH TLV: S,200PPM/250STEL; 93
EPA Rpt Qty: 5000 LBS
DOT Rpt Qty: 5000 LBS
Ozone Depleting Chemical: N

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Health Hazards Data

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LD50 LC50 Mixture: NONE SPECIFIED BY MANUFACTURER.
Route Of Entry Inds - Inhalation: YES
Skin: YES
Ingestion: YES
Carcinogenicity Inds - NTP: NO
IARC: NO
OSHA: NO

Exhibit - A
USSN 09/758,978
Torok et al.

Effects of Exposure: SWALLOWING THE LIQUID CAUSES INEBRIATION, HEADACHE, NAUSEA AND VOMITING LEADING TO SEVERE ILLNESS, BLINDNESS AND PERHAPS DEATH. LIQUID CAUSES EYE IRRITATION. MAY BE FATAL OR CAUSE BLINDNESS IF SWALLOW ED.

Explanation Of Carcinogenicity: NOT RELEVANT

Signs And Symptions Of Overexposure: SEE HEALTH HAZARDS.

Medical Cond Aggravated By Exposure: NONE SPECIFIED BY MANUFACTURER.

First Aid: SKIN: FLUSH WITH PLENTY OF WATER. EYES: FLUSH WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. GET MEDICAL CARE FOR EYES. INGEST: INDUCE VOMITING @ ONCE. THEN GIVE 2 TABLESPOONS OF BAKING SODA & A GLASS OF WATER. CALL A PHYSICIAN @ ONCE. INHAL: REMOVE TO FRESH AIR. SUPPORT BRTHG (GIVE O*2/ARTF RESP) (FP N).

Handling and Disposal

Spill Release Procedures: FLUSH SPILLED MATERIAL WITH LARGE VOLUME OF WATER.

Neutralizing Agent: NONE SPECIFIED BY MANUFACTURER.

Waste Disposal Methods: WASH WITH WATER DOWN THE DRAIN. DISPOSE OF I/A/W FEDERAL, STATE & LOCAL REGULATIONS (FP N).

Handling And Storage Precautions: DO NOT LEAVE CONTAINER OPEN. AVOID PROLONGED OR REPEATED CONTACT WITH SKIN.

Other Precautions: NONE SPECIFIED BY MANUFACTURER.

Fire and Explosion Hazard Information

Extinguishing Media: CARBON DIOXIDE OR DRY CHEMICAL FOR SMALL FIRES. ALCOHOL OR POLYMER FOAM FOR LARGE FIRES.

Fire Fighting Procedures: WEAR NIOSH/MSHA APPROVED SCBA AND FULL PROTECTIVE EQUIPMENT (FP N). ADDITION OF WATER REDUCES INTENSITY OF FLAME.

Unusual Fire/Explosion Hazard: NONE SPECIFIED BY MANUFACTURER.

Control Measures

Respiratory Protection: USE NIOSH/MSHA APPROVED RESPIRATOR APPROPRIATE FOR EXPOSURE OF CONCERN (FP N).

Ventilation: GEN(MECH): ACCEPTABLE. LOCAL EXHAUST: PREFERABLE.

Protective Gloves: PLASTIC GLOVES.

Eye Protection: CHEMICAL WORKERS GOGGLES (FP N).

Other Protective Equipment: IMPERVIOUS APRON & BOOTS, EYE BATH, SHOWER.

Work Hygienic Practices: NONE SPECIFIED BY MANUFACTURER.

Supplemental Safety and Health: NONE SPECIFIED BY MANUFACTURER.

Physical/Chemical Properties

HCC: F5

B.P. Text: 141F,61C

Vapor Pres: 97

Solubility in Water: VERY SOLUBLE

Appearance and Odor: DARK GREEN

Reactivity Data

Stability Indicator: YES

Stability Condition To Avoid: HEAT, SPARKS, FIRES.

Materials To Avoid: NONE SPECIFIED BY MANUFACTURER.

Hazardous Decomposition Products: NONE SPECIFIED BY MANUFACTURER.

Hazardous Polymerization Indicators: NO

Conditions To Avoid Polymerization: NOT RELEVANT

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Toxicological Information
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Ecological Information
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MSDS Transport Information
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Regulatory Information
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Other Information
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=====
Transportation Information
=====
Responsible Party Cage: IO419
Trans ID NO: 40609
Product ID: BROMTHYMOL BLUE INDICATOR SOLN, 170-S
MSDS Prepared Date: 06/19/1992
Review Date: 05/05/1993
Article W/O MSDS: N
Multiple KIT Number: 0
Unit Of Issue: NK
Container QTY: NK
=====
Detail DOT Information
=====
DOT PSN Code: JEZ
Symbols: I
DOT Proper Shipping Name: METHANOL
DOT PSN Modifier: METHYL ALCOHOL SEE METHANOL
Hazard Class: 3
UN ID Num: UN1230
DOT Packaging Group: II
Label: FLAMMABLE LIQUID, POISON
Special Provision: T8
Non Bulk Pack: 202
Bulk Pack: 242
Max Qty Pass: 1 L
Max Qty Cargo: 60 L
Vessel Stow Req: B
Water/Ship/Other Req: 40
=====
Detail IMO Information
=====
IMO PSN Code: JPB
IMO Proper Shipping Name: METHANOL
IMDG Page Number: 3251
UN Number: 1230
UN Hazard Class: 3.2
IMO Packaging Group: II
Subsidiary Risk Label: TOXIC
EMS Number: 3-06
MED First Aid Guide NUM: 306
=====
Detail IATA Information
=====
```

IATA PSN Code: QHQ
 IATA UN ID Num: 1230
 IATA Proper Shipping Name: METHANOL
 IATA UN Class: 3
 Subsidiary Risk Class: 6.1
 IATA Label: FLAMM. LIQ. & TOXIC
 UN Packing Group: II
 Packing Note Passenger: 305
 Max Quant Pass: 1L
 Max Quant Cargo: 60L
 Packaging Note Cargo: 307
 Exceptions: A104, A113

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Detail AFI Information

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AFI PSN Code: QHQ
 AFI Proper Shipping Name: METHANOL OR METHYL ALCOHOL
 AFI Hazard Class: 3
 AFI UN ID NUM: UN1230
 AFI Packing Group: II
 AFI Label: 6.1
 Special Provisions: P4
 Back Pack Reference: A7.3

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HAZCOM Label

=====

Product ID: BROMTHYMOL BLUE INDICATOR SOLN, 170-S
 Cage: IO419
 Company Name: ORBECO ANALYTICAL SYSTEMS INC
 Street: 185 MARINE ST
 City: FARMINGDALE NY
 Zipcode: 11735 US
 Health Emergency Phone: 516-293-4110
 Date Of Label Review: 11/05/1992
 Label Date: 11/05/1992
 Chronic Hazard IND: N
 Eye Protection IND: YES
 Skin Protection IND: YES
 Signal Word: DANGER
 Respiratory Protection IND: YES
 Health Hazard: Severe
 Contact Hazard: Slight
 Fire Hazard: Severe
 Reactivity Hazard: None
 Hazard And Precautions: FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS, OPEN
 FLAME. ACUTE: LIQUID CAUSES EYE IRRITATION. INGESTION CAUSES
 INEBRIATION, HEADACHE, NAUSEA, & VOMITING LEADING TO SEVERE ILLNESS,
 BLINDNESS, AND DEATH. CHR ONIC: NONE SPECIFIED BY MANUFACTURER.

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 a military or civilian employee of the United States of America should
 seek competent professional advice to verify and assume responsibility
 for the suitability of this information to their particular situation

regardless of similarity to a corresponding Department of Defense or other government situation.

Material Safety Data Sheet

BROMTHYMOL BLUE, .04%

Carolina Biological Supply Company

Page 1 of 2

Revised 1/2/98

Replaces 5/12/97

Printed 10/01

1. PRODUCT DESCRIPTION

Product Name: Bromthymol Blue, 0.04%
Product Code (s): 84-9161, 84-9163, 84-9165, 95-7860,
20-2275, 20-6070, 84-0522
Size: 25 mL, 120 mL, 500 mL
Chemical Name: Does not apply, product is a mixture
CAS Number: No data available
Formula: See section 2
Synonyms: None known
Distributor: Carolina Biological Supply Company
2700 York Road
Burlington, NC 27215

Chemical Emergency Information:
800-227-1150 (8am-5pm [ET] M-F)
Chemtrec (Transportation Spill Response 24 hours):
800-424-9300

2. COMPOSITION/INFORMATION ON INGREDIENTS

Principle Hazardous Components: Bromthymol Blue (CAS#
76-59-5) 0.04%

TLV and PEL units: None established

3. HAZARDOUS IDENTIFICATION

Emergency Overview:

Potential Health Effects:

Eyes: May cause irritation

Skin: May cause irritation

Ingestion: May cause gastrointestinal discomfort

Inhalation: May cause irritation to respiratory tract

4. FIRST AID MEASURES

Emergency and First Aid Procedures:

Eyes - Flush with water for at least 15 minutes, raising and
lowering eyelids occasionally. Get medical attention if
irritation persists.

Skin - Thoroughly wash exposed area for at least 15 minutes.
Remove contaminated clothing. Launder contaminated
clothing before reuse. Get medical attention if irritation
persists.

Ingestion - If swallowed, if conscious, give plenty of water.
Immediately call a physician or poison control center. Never
give anything by mouth to an unconscious person.

Inhalation - Remove to fresh air. Give oxygen if breathing is
difficult; give artificial respiration if breathing has stopped.
Keep person warm, quiet, and get medical attention.

5. FIREFIGHTING PROCEDURES

Flash Point (Method Used): No data available

NFPA Rating: Health: 0

Fire: 0

Reactivity: 0

Extinguisher Media: Use media suitable to extinguish
surrounding fire

Flammable Limits in Air % by Volume: No data available

Autoignition Temperature: No data available

Special Firefighting Procedures: Firefighters should wear full
protective equipment and NIOSH approved self-contained
breathing apparatus

Unusual Fire and Explosion Hazards: None expected

6. SPILL OR LEAK PROCEDURES

Steps to be Taken in Case Material is Released or Spilled:

Ventilate area of spill. Eliminate all sources of ignition.

Remove all non-essential personnel from area. Clean-up
personnel should wear proper protective equipment and
clothing. Absorb material with suitable absorbant and
containerize for disposal.

7. SPECIAL PRECAUTIONS

Precautions to be Taken in Handling or Storing: Store at room
temperature. Do not take internally.

Other Precautions: Wash thoroughly after handling

8. SPECIAL PROTECTION INFORMATION

Respiratory Protection (Specify Type): A NIOSH/MSHA
chemical cartridge respirator should be worn if PEL or TLV
is exceeded.

Ventilation:

Local Exhaust: Yes

Mechanical (General): Yes

Special: Not generally needed

Other: No

Protective Gloves: Rubber, neoprene, PVC, or equivalent

Eye Protection: Splash-proof chemical safety goggles should be
worn at all times

Other Protective Clothing or Equipment: Lab coat, eye wash,
and safety shower

Exhibit - B
USSN 09/758,978
Torok et al.

Material Safety Data Sheet

BROMTHYMOL BLUE, .04% (CONT.)

Carolina Biological Supply Company

Page 2 of 2

Revised 1/2/98

Replaces 5/12/97

Printed 10/01

9. PHYSICAL DATA

Molecular Weight: No data available
Melting Point: Approximately 100 °C
Boiling Point: Approximately 100 °C
Vapor Pressure: Approximately 17.5 @ 20 °C
Vapor Density (Air-1): No data available
Specific Gravity (H₂O=1): Approximately 1
Percent Volatile by Volume: 100%
Evaporation Rate (Ether=1): Approximately 1
Solubility in Water: Complete, product is an aqueous solution
Appearance and Odor: Clear blue liquid, odorless

10. REACTIVITY DATA

Stability: Stable
Conditions to Avoid: No data available
Incompatibility (Materials to Avoid): Water reactive materials
Hazardous Decomposition Products: None known
Hazardous Polymerization: Will not occur

11. TOXICITY DATA

Toxicity Data: Bromthymol Blue: No toxicity found
Effects of Overexposure:
Acute: See section 3
Chronic: Bromthymol Blue: No chronic effects data found.
Not listed as causing cancer by IARC, NTP, or OSHA
Conditions Aggravated by Overexposure: No data available.
Target Organs: No data available
Primary Route(s) of Entry: No data available

12. ECOLOGICAL DATA

EPA Waste Numbers: None

13. DISPOSAL INFORMATION

Waste Disposal Methods: Dispose in accordance with all applicable federal, state and local regulations. Always contact a permitted waste disposer (TSD) to assure compliance.

14. TRANSPORT INFORMATION

DOT Proper Shipping Name: Non-regulated material

15. REGULATORY INFORMATION

EPA TSCA Status: On TSCA Inventory
Hazard Category for SARA Section 311/312 Reporting: Acute

SARA Sec. 313

Product or Components	SARA EHS Sec. 302 TPQ	Chemicals Name List	CERCLA RCRA Sec. 103 RQ	Sec. 261.33
		Category		
Bromthymol Blue, 0.04%	No	No	No	No

16. ADDITIONAL INFORMATION

The information provided in this Material Safety Data Sheet represents a compilation of data drawn directly from various sources available to us. Carolina Biological Supply makes no representation or guarantee as to the suitability of this information to a particular application of the substance covered in the Material Safety Data Sheet. Any employer must carefully assess the applicability of any information contained herein in regards to the particular use to which the employer puts the material.

Glossary

ACGIH American Conference of Governmental Industrial Hygienists

CAS Number Chemical Services Abstract Number

CERCLA Comprehensive Environmental Response, Compensation, and Liability Act

DOT U.S. Department of Transportation

IARC International Agency of Research on Cancer

N/A Not Available

NTP National Toxicology Program

OSHA Occupational Safety and Health Administration

PEL Permissible Exposure Limit

ppm parts per million

RCRA Resource Conservation and Recovery Act

SARA Superfund Amendments and Reauthorization Act

TLV Threshold Limit Value

TSCA Toxic Substances Control Act